

B3 caused by pathogenic bacteria a composition containing an effective amount of a dietary fiber or a mixture of dietary fibers.

Please add the following new claims:

--23. The method of Claim 17, wherein the human or vertebrate is an adult human and the amount of fiber administered to the adult human ranges from 5 to 40 g/day.

B4 24. The method of Claim 17, wherein the human or vertebrate is an adult human and the amount of fiber administered to the adult human ranges from 5 to 25 g/day.

Sub C 25. The method of Claim 12, wherein the human or vertebrate is an adult human and the amount of fiber administered to the adult human ranges from 5 to 40 g/day.

26. The method of Claim 12, wherein the human or vertebrate is an adult human and the amount of fiber administered to the adult human ranges from 5 to 25 g/day.--

REMARKS

By the above amendment, Claims 1, 4-7 and 15 have been canceled and Claims 23-26 have been added. Claims 8-14 and 16-26 are therefore pending.

Claims 1 and 4-22 were rejected under 35 USC 103(a) as being allegedly unpatentable over Green (U.S. Patent No. 5,792,754). This rejection, which appears on pages 3 and 4 of the Official Action, is respectfully traversed for the following reasons.

To establish a *prima facie* case of obviousness, three basic criteria must be met. First, there must be some suggestion or motivation, either in the references themselves or in the knowledge generally available to one of ordinary skill in the art, to modify the reference or to combine reference teachings. Second, there must be a reasonable expectation of success. Finally, the prior art reference (or references when combined) must teach or suggest all of the

claim limitations. The teaching or suggestion to make the claimed combination and the reasonable expectation of success must both be found in the prior art, and not based on Applicant's disclosure. In re Vaeck, 947 F.2d 488, 20 USPQ2d 1438 (Fed. Cir. 1991). See MPEP § 2142.

Independent Claims 8 and 20 were rejected under 35 USC 103(a) as being allegedly unpatentable over Green. Claim 8 recites “[a] method for the prevention of systemic infections in humans or vertebrates comprising *administering to humans or vertebrates at an increased risk for systemic infections* a composition containing an effective amount of a dietary fiber or a mixture of dietary fibers” [emphasis added]. Claim 20 recites “[a] method for the inhibition and/or treatment of systemic infections in humans or vertebrates comprising *administering to humans or vertebrates having a systemic infection caused by pathogenic bacteria* a composition containing an effective amount of a dietary fiber or a mixture of dietary fibers” [emphasis added]. According to the Official Action, Green teaches a “nutritional” composition which “. . . may be used to clear toxic compounds from the intestines by providing stool bulk and substrate for intestinal flora” (paragraph spanning pages 3 and 4 of the Official Action).

There is no teaching or suggestion in Green, however, of a method for *the prevention of systemic infections* as set forth in Claims 8 or of a method for *the inhibition and/or treatment of systemic infections* as set forth in Claim 20. Moreover, Claims 8 and 20 are directed to *a method of use* of a dietary fiber composition and not to the dietary fiber composition itself. The Official Action alleges that “. . . it is inherent to receive the body-wide therapeutic benefits associated with consuming such a composition” (see page 2 of the Official Action dated January 14, 2002). Whether or not any particular property of a composition is inherent, however, is not dispositive of the patentability of the method of use of the composition. Thus, it is well established that a new and unobvious use of even a known composition may be patentable as a process or method of

using the composition. In re Hack, 245 F.2d 246, 248, 114 USPQ 161, 163 (CCPA 1957). See MPEP § 2112.02. This rationale also extends to methods of treatment using compounds having a known pharmacological activity. See, for example, In re Merck & Co., Inc., 231 USPQ 375 (Fed. Cir. 1986). In Merck, the CAFC analyzed claims directed to the method of use of amitriptyline to treat depression. The prior art taught that amitriptyline was a psychotropic drug which reacted on the central nervous system. However, the drug was not known to be an antidepressant. The CAFC stated that, “in order to show obviousness, *it was necessary to determine from knowledge already available in the art at the time of appellant's invention that one skilled in the medicinal chemical art would have expected amitriptyline to be useful in the treatment of depression in humans*” [emphasis added]. Merck, *supra*, 231 USPQ at 378.

Therefore, in order to establish a *prima facie* case of obviousness for the subject matter of Claims 8 and 20, it would be necessary to establish that one of ordinary skill in the art would have expected a dietary fiber or a mixture of dietary fibers to be useful in the prevention of systemic infections (Claim 8) or in the treatment and/or inhibition of systemic infections (Claim 20) in humans or vertebrates. The Official Action has pointed to no teaching or suggestion in Green or in any other reference that would suggest a method as claimed for either the prevention or for the inhibition and/or treatment of systemic infections in humans or vertebrates. It is therefore respectfully requested that the rejection of Claims 8 and 20 be withdrawn.

For at least the reasons set forth above, it is also respectfully submitted that Claims 9-14 and 21, which depend either directly or indirectly from Claim 8, and Claims 16-19 and 22, which depend from Claim 20, are also patentable over the art of record. Accordingly, it is respectfully requested that the rejection of these claims also be reconsidered and withdrawn.

Additionally, Claims 13, 14, 18 and 19 can be further distinguished from Green as set forth below. Claims 13 and 18 depend indirectly from Claims 8 and 20 respectively and further

recite that “. . . the fiber is chicory inulin with an average degree of polymerization (\overline{DP}) of at least 20.” Claims 14 and 19 also depend indirectly from Claims 8 and 20, respectively, and further recite that “. . . the fiber is chicory inulin with an average degree of polymerization (\overline{DP}) of at least 25.” The Official Action acknowledges that Green “. . . does not expressly teach inulin with an average degree of polymerization” (see page 4 of the Official Action dated January 14, 2001). The Official Action, however, further states that “. . . it would have been obvious to one having ordinary skill in the art at the time the invention was made to substitute key components of the referenced invention for key components of the claimed invention . . . with the objective of providing a synergistic combination of fibrous material to aid in gut function and maintenance of optimal intestinal wall conditions” (see page 4 of the Official Action dated January 14, 2002).

The Official Action, however, has failed to indicate where *in the prior art* the suggestion or motivation to modify the teachings of Green to arrive at the invention set forth in Claims 13 and 14 can be found. Rather, the Official Action merely concludes that such a modification would have been obvious without providing a suggestion *in the prior art* of the desirability of modifying the teachings of Green. Accordingly, it is respectfully submitted that Claims 13, 14, 18 and 19 can be further distinguished from Green. Reconsideration and withdrawal of the rejection of these claims is therefore respectfully requested.

Claims 21 and 22 can also be further distinguished from Green. Claim 21 depends from Claim 8 and further recites that “. . . the pathogenic bacteria is selected from the group consisting of *Clostridia*, *Bacteroides*, *Listeria*, *Candida* and *Salmonella*”. Claim 22 depends from Claim 20 and further recites that “. . . the pathogenic bacteria is selected from the group consisting of *Clostridia*, *Bacteroides*, *Listeria*, *Candida* and *Salmonella*”. There is no teaching or suggestion

in Green of a method of preventing or a method of treating and/or inhibiting a systemic infection caused by pathogenic bacteria selected from the group consisting of *Clostridia*, *Bacteroides*, *Listeria*, *Candida* and *Salmonella* as set forth in Claims 21 and 22.

Claims 23 - 26 are also further distinguishable from Green. Claims 23 and 25 depend indirectly from Claims 20 and 8, respectively and further recite that “. . . the human or vertebrate is an adult human and the amount of fiber administered to the adult human ranges from 5 to 40 g/day. Claims 24 and 26 also depend indirectly from Claims 20 and 8, respectively and further recite that “. . . the human or vertebrate is an adult human and the amount of fiber administered to the adult human ranges from 5 to 25 g/day. There is no teaching or suggestion in Green of a method of preventing or a method of treating and/or inhibiting a systemic infection caused by pathogenic bacteria in an adult human comprising administering from 5 to 40 g/day or from 5 to 25 g/day of fructan as set forth in Claims 22-26.

In the “Response to Arguments” section, the Official Action states that the “[a]pplicant has not shown any unexpected results obtained by utilizing inulin with the claimed average DP (degree of polymerization)” (see page 3 of the Official Action dated January 14, 2002). It is respectfully submitted, however, that the Applicant is under no duty to provide a showing of unexpected results. Rather, evidence of unexpected results can be used by an applicant to rebut a *prima facie* case of obviousness. See MPEP sec. 716.02(a). In fact, it is well established that “[t]he lack of objective evidence of nonobviousness does not weigh in favor of obviousness”. Miles Labs. Inc. v. Shandon Inc., 997 F.2d 870, 878, 27 USPQ2d 1123, 1129 (Fed. Cir. 1993). See MPEP sec. 716.01(a). As set forth above, the Official Action has failed to establish a *prima facie* case of obviousness. Accordingly, it is respectfully submitted that a showing of unexpected results is not necessary to patentably distinguish the instant claims from Green.

Further, there is in fact objective evidence of non-obviousness in the present case which further distinguishes the claimed invention from Green. For example, Figures 1 and 2 graphically illustrate the effect of fiber type on the mortality of mice infected with *Listeria monocytogenes* and *Salmonella typhimurium*, respectively. In particular, Figures 1 and 2 illustrate that mice fed a diet including inulin fiber had a significantly lower mortality rate than mice fed a diet containing cellulose. Further, the inulin product with the higher average degree of polymerization had an even more pronounced beneficial effect on the mortality rate. According to MPEP § 716.01(a), objective evidence of non-obviousness *must be considered* whenever present. Further, “[e]xaminers must consider comparative data in the specification which is intended to illustrate the claimed invention in reaching a conclusion with regard to the obviousness of the claims”. In re Margolis, 785 F. 2d 1029, 228 USPQ 940 (Fed. Cir. 1986). It is respectfully submitted that the evidence of non-obviousness as set forth in the Specification further distinguishes the claimed invention from Green. Accordingly, it is respectfully requested that this objective evidence of non-obviousness be considered.

CONCLUSION

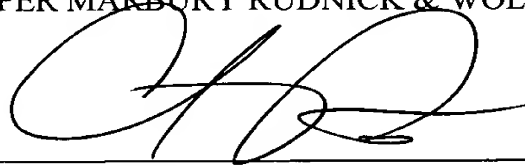
In view of the above remarks, it is respectfully submitted that Claims 1 and 4-22 are patentable over the references of record. Reconsideration and withdrawal of the rejection of Claims 8 - 14 and 16 - 26 is therefore respectfully requested.

Since all of the pending claims are believed to be in condition for allowance, prompt issuance of a Notice of Allowability is respectfully requested.

If there are any other questions, the Examiner is encouraged to call the undersigned attorney at the phone number listed below.

Respectfully submitted,

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A handwritten signature in black ink, appearing to be 'S. Kelber', written over a horizontal line.

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MARKED-UP COPY OF AMENDED CLAIMS

8. (Amended) A method for the prevention of systemic infections in humans or vertebrates caused by pathogenic bacteria comprising administering to [said] humans or vertebrates at an increased risk of developing systemic infections a composition containing an effective amount of a dietary fiber or a mixture of dietary fibers.

16. (Amended) The method according to Claim [15] 20, wherein the dietary fiber is selected from the group consisting of lignin, cellulose, hemicellulose, pectin, gums, arabic gum, carrageenan, waxes, resistant oligosaccharides, oligofructose, resistant polysaccharides, resistant starch and fructan.

20. (Amended) A method for the inhibition and/or treatment of systemic infections in humans or vertebrates [caused by pathogenic bacteria] comprising administering to [said] humans or vertebrates having a systemic infection caused by pathogenic bacteria a composition containing an effective amount of a dietary fiber or a mixture of dietary fibers.